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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,763	05/12/2005	Heinz Peter Vollmers	043043-0358749	8912

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PILLSBURY WINTHROP SHAW PITTMAN LLP

ATTENTION: DOCKETING DEPARTMENT

P.O BOX 10500

McLean, VA 22102

EXAMINER

HALVORSON, MARK

ART UNIT

PAPER NUMBER

1642

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08/05/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/506,763

Applicant(s)

VOLLMERS ET AL.

Examiner

Mark Halvorson

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 79 and 95-105 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 102 is/are allowed.
- 6) ☒ Claim(s) 79, 95-101 and 103-105 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 79 and 95-105 are pending and under examination.

35 USC § 112 1st paragraph rejection withdrawn

The rejection of claims 79, 95-101 and 103 for failing to comply with the written description requirement is withdrawn in view of Applicants amendments to the claims.

The rejection of claims 100 and 101 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is withdrawn in view of Applicants' amendments to claims 100 and 101.

NEW REJECTIONS:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 79, 95-101 and 103-105 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a genus of purified antibodies that specifically binds to an epitope of an antigen expressed by at least one of HT-29, CACO-2, COLO-320 or COLO-678 cells, wherein CM-1 antibody specifically binds to said epitope of the antigen expressed by at least one of HT-29, CACO-2, COLO-320 or COLO-678 cells.

The specification discloses an IgM antibody, CM-1, that induces apoptosis of a neoplastic cell but does not induce apoptosis of a non-neoplastic cell wherein the antibody specifically binds to at least one of HT-29, CACO-2, COLO-320, COLO-206F, or COLO-678 cells, the antibody comprising a heavy chain variable region consisting of the amino acid sequence of SEQ ID NO: 1, and a light chain variable region consisting of SEQ ID NO:3. Neither the specific epitope nor the specific antigen bound by the claimed antibody is disclosed. Thus, as in *In re Alonso*, (Fed Cir 2008) the specification teaches nothing about the structure, epitope characterization, binding affinity specificity or pharmacologic properties common to the large genus of antibodies encompassed by the present claims.

The Federal Circuit addressed the application of the written description requirement to DNA-related inventions in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The court stated that "[a] written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *Id.* At 1567, 43 USPQ2d at 1405. The court concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." *Id.*

The Federal Circuit has recently clarified that a molecule can be adequately described without disclosing its complete structure. See Enzo Biochem, Inc. V. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court adopted the standard that the written description requirement can be met by "show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristicsi.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." *Id.* At 1324, 63 USPQ2d at 1613 (emphasis omitted, bracketed material in original).

Thus, the instant specification may provide an adequate written description of the genus of antibodies, per Lilly by structurally describing a representative number of

antibodies that function as claimed or by describing structural features common to the members of the genus, which features constitute a substantial portion of the genus. Alternatively, per Enzo, the specification can show that the claimed invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.

In this case, the specification does not describe the genus of antibodies in a manner that satisfies either the Lilly or Enzo standards. There are insufficient structural features common to all members of the genus of antibodies. The genus of antibodies encompasses any antibody that competes with the binding of the antibody CM-1 to at least one of HT-29, CACO-2, COLO-320 or COLO-678 cells. Applicants have only identified one antibody, CM-1, comprising the amino acid sequences of SEQ ID NOs: 1 and 3 that binds to the epitope on at least one of HT-29, CACO-2, COLO-320, COLO-206F, or COLO-678 cells. The specification does not characterize the antigen to which the antibodies must bind and thus the common structural features of the genus of antibodies is unknown. This description is not sufficient to describe the unlimited number of antibodies in the claimed genus. For purposes of satisfying the written description requirement, it is not enough merely to disclose a method of making and identifying compounds capable of being used to practice the claimed invention. Applicants have not described the antigen bound by the genus of antibodies sufficiently to demonstrate that they had possession of the claimed genus of antibodies that bound this antigen.

Applicants have also not disclosed sufficiently detailed, relevant identifying characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. Applicants are not in possession of the epitope bound by CM-1. The specification only discloses that CM-1 specifically binds to at least one of HT-29, CACO-2, COLO-320, COLO-206F, or COLO-678 cells. As indicated above, Applicants have not characterized the antigen to which the antibodies must bind. Thus, the genus of antibodies is described by its functional characteristics, their ability to compete with CM-

1 for binding to at least one of HT-29, CACO-2, COLO-320, COLO-206F, or COLO-678 cells. The specific antigen bound by CM-1 was not been adequately described and thus the structure of the antibodies that bind the unknown antigen has not been sufficiently described. Although the requirement for written description may be met by functional characteristics when these characteristics are coupled with a known or disclosed correlation between function and structure, Applicants have not disclosed sufficient correlation between the functional characteristics of the genus of antibodies and the structure of these antibodies. Applicants have only described one antibody that binds to at least one of HT-29, CACO-2, COLO-320, COLO-206F, or COLO-678 cells and have not characterized the antigen to which the genus of antibodies must bind other than it is expressed on one of HT-29, CACO-2, COLO-320, COLO-206F, or COLO-678 cells.

The specification does not provide an adequate written description of the genus antibodies of claims 79, 95-101 and 103-105 that is required to practice the claimed invention. Applicants have not described the genus of antibodies sufficiently to show they had possession of the claimed genus.

Summary

Claims 79-101 and 103 are rejected.

Claim 102 is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Halvorson, PhD whose telephone number is (571) 272-6539. The examiner can normally be reached on Monday through Friday from 8:30am to 5 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832. The fax phone number for this Art Unit is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Art Unit: 1642

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Mark Halvorson/
Examiner, Art Unit 1642